K103842

510(k) Summary
UniCel® DxC SYNCHRON® Clinical Systems Software Version 5.0

1.0 Submitted By:

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APR 27 2011

2.0 Date Submitted

December 29, 2010

3.0 Device Name(s):

3.1 Proprietary Names

UniCel® DxC 800 SYNCHRON® System Software Version 5.0

3.2 Classification Name

Discrete photometric chemistry analyzer for clinical use [862.2160]
21CFR Sec.- 862.1345 Glucose test system

4.0 Legally Marketed Device

Candidate(s)	Predicate	Manufacturer	Document Number
UniCel® DxC 800 SYNCHRON® System Software Version 5.0	UniCel® DxC 600/800 SYNCHRON® System Software Version(s) 1.0 and 1.4	Beckman Coulter, Inc.	K042291, K060256

The UniCel® DxC 800 SYNCHRON® System Software Version 5.0 claim substantial equivalence to the UniCel® DxC 600/800 SYNCHRON® System Software Version(s) 1.0 (Docket Number K042291) and 1.4 (Docket Number K060256), currently in commercial distribution.

5.0 Device Description

The UniCel® DxC 800 SYNCHRON® System equipped with Software Version 5.0 is member of the SYNCHRON family of clinical chemistry analyzers, manufactured and distributed by Beckman Coulter, Inc. The SYNCHRON instrument family includes the SYNCHRON CX Clinical Chemistry Systems (CX4/CE/Δ/PRO, CX5/CE/Δ/PRO, CX7/RTS/Δ/PRO, CX9ALX/PRO), and the SYNCHRON LX Clinical Chemistry Systems (LX20/PRO/LXi 725). The UniCel DxC Systems are distinguished from other SYNCHRON systems in that they utilize more advanced hardware and software to improve system robustness and serviceability, and offer enhancements and features for user convenience. The analyzers operate in conjunction with reagents, calibrators, and controls designed for use with SYNCHRON Systems.

6.0 Intended Use

The UniCel DxC 800 System Software Version 5.0 is a fully automated, computer-controlled clinical chemistry analyzers intended for the in vitro determination of a variety of cleared clinical laboratory assays, such as glucose.

GLUCm reagent is intended for the quantitative determination of glucose concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

7.0 Comparison to the Predicate

In this submission, Beckman is seeking clearance for the UniCel DxC 800 System equipped with Software Version 5.0.
To demonstrate substantial equivalence, the notification centers on a comparison of software and hardware to the predicate UniCel DxC 600/800 platforms, and demonstrates performance characteristics of a representative chemistry menu. Selected reagent test systems will demonstrate that both the module chemistry (MC) and the cartridge chemistry (CC) section of the UniCel DxC Software Version 5.0 Systems provide equivalent performance to that of current UniCel DxC Systems.

8.0 Summary of Performance Data

Performance data from validation testing (provided in the "Performance Characteristics" section of this submission) supports equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

APR 27 2011

Beckman Coulter, Inc.
c/o Marine Boyajian
Senior Regulatory Affairs Specialist
250 S. Kraemer Boulevard, Mail Stop E2 Se08
Brea, CA 92821

Re: k103842
Trade/Device Name: UniCel DxC 800 Synchron System Software Version 5.0
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II, I
Product Code: CGA, JJE
Dated: March 30, 2011
Received: March 31, 2011

Dear: Marine Boyajian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K103842

Device Name: UniCel® DxC 800 SYNCHRON® Clinical System Software Version 5.0

Indication For Use:

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Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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